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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/023,483	02/13/98	HEROUX	J 2528-2

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HM22/0308

EXAMINER	
TUNG, J	
ART UNIT	PAPER NUMBER

1656
DATE MAILED: 03/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/023,483

Applicant(s)
Heroux et al.

Examiner
Joyce Tung

Group Art Unit
1656



☒ Responsive to communication(s) filed on Sep 7, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-40 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-40 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Amendment

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1656.

1. Applicants' arguments, filed 9/07/99, have been fully considered but they are not deemed to be persuasive. Rejections and /or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. Regarding the rejection of claims 1-3, 6-12, 14-25, 28-32 and 34-37 under 35 U.S.C. 103(a) over Hartley in view of Eberle et al., the response argues that Hartley uses random primers as generic reagent for amplifying nucleic acid but only describes assays for specific DNA sequence. However, the disclosure of Hartley indicates that the amplification may be performed without prior knowledge of specific sequence (See the Abstract), the method can be used for detection (See column 8, lines 51-55) and the method may also be desirable in the quantification of the amplification products (See column 6, lines 36-43). Additionally, since the preamble of instant claims is worded as "a method for detection and/or quantitation of nucleic acid", it is unclear whether the method is for detection or quantitation or both. The nucleic acid used in instant invention is not specified by that the nucleic acid is a specific nucleic acid or an unknown nucleic acid sequence.

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The response further argues that Eberle et al. do not describe methods for quantitating nucleic acids in which nucleic acid is defined known concentration. Eberle et al. do disclose that the method can be used for detection (See column 1, lines 5-12). Since the method of Eberle et al. is reliable and sensitive, an artisan of ordinary skill in the art would have applied the technique of Eberle et al. and combined with the method of Hartley to detect or quantify a nucleic acid in a sample for a reasonable expectation of success. Thus, the rejection is maintained.

3. Claims 1-3, 6-12, 14-25, 28-32 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272) in view of Eberle et al. (5,413,906).

4. Regarding the rejection of claims 4, 5, 13, 26, 27 and 33 under 35 U.S.C. 103(a) over Hartley in view of Wu et al. and Respass. The response argues that the amplified products have binding species because they hybridize to bound probe and by using itself as the binding species, the assay can be used for a known nucleic acid sequence. This does not necessarily suggest that the nucleic acid sequence to be detected or quantified is a known nucleic acid sequence because the binding species can be any thing attached to the amplified nucleic acid products. Further, the reference of Hartley is discussed in section 2 above. Thus, the rejection is maintained.

5. Claims 4, 5, 13, 26, 27 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272) in view of Wu et al. (Genomics, 1989, vol. 4, pg. 560-569) and Respass (5,599,662).

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6. The newly added claim 38 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272) in view of Eberle et al. (5,413,906) with the same reasons as set forth in section 4 of the first Office action mailed 3/4/99.

7. The newly added claims 39-40 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272) in view of Wu et al. (Genomics, 1989, vol. 4, pg. 560-569) with the same reasons as set forth in section 5 of the first Office action mailed 3/4/99.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

March 3, 2000


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

3/7/2000